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09/582,152	09/05/2000	Christopher Raymond Jones	00456/HG	6861

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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/09/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/582,152

Applicant(s)

JONES ET AL.

Examin r

San-ming Hui

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,9,12-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,9,12-16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

A substituted specification and claims filed January 16, 2002 is entered and acknowledged.

Cancellation of claims 2, 6-8, 10-11, and 17 in the amendment filed January 16, 2002 is acknowledged.

The amendment of claims 1, 3, 4, and 13 filed January 16, 2002 is acknowledged.

Claims 18-21 are newly added claims in amendment filed January 16, 2002.

The outstanding objection of claim 14 is withdrawn in view of the substituted pages of claims filed January 16, 2002.

The outstanding rejections of claims 3 and 4 under 35 USC 112, second paragraph are withdrawn in view of the amendment filed January 16, 2002.

The outstanding rejections of claims 1, 2, and 16-17 under 35 USC 102 are withdrawn in view of the amendment filed January 16, 2002.

Claims 1, 3-5, 9, 12-16, and 18-21 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 9, 12-16, and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for any

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non-surfactant biopenetrant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There is no adequate direction provided by the applicant as to how to select a suitable biopenetrants to be used in the invention to form a synergistic anti-microbial composition and remove microbes in aqueous system. Furthermore, the instant specification does not provide any working examples to show how non-surfactant biopenetrants may be used successfully in the invention to form a synergistic anti-microbial composition and remove microbes in aqueous system.

Moreover, it is known in the art that different compounds may have different potency and activity because of the structural and conformational differences in the compounds. Therefore a different biopenetrants may be reasonably expected to yield a different result in a synergistic anti-microbial composition or in a method of inhibit microbes in aqueous system. Due to this unpredictability, it would prevent the skilled artisan from determining compounds which may be termed an "biopenetrant" to retain the desired function of the instant invention to form a synergistic anti-microbial composition and remove microbes in aqueous system without undue experimentation.

Please note that claims 1, 13, and 18 recite a limitation "synergistic" and "non-surfactant biopenetrant synergist" in line 1 and line 3 respectively. Synergism is an unexpected and highly unpredictable effect. Applicant must demonstrate such an unexpected result for a representative number of compounds of the very broad genus herein (See MPEP 716.02(b)). Synergism should be demonstrated with evidence that

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the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to synergism (i.e., unexpected benefits) must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, such evidence to demonstrate synergism is not present.

Response to arguments regarding rejections under 35 USC 112, first paragraph

Applicant's remarks filed January 16, 2002 regarding synergism being demonstrated in example 1 in the specification, page 17-20 have been considered but are not found persuasive because synergism is not clearly demonstrated therein. Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (See MPEP 716.02(a)). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, example 1 merely compares the combination of the instant claimed composition against other commercial combination products. It is

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not clear whether those products are the closest standard for the comparison of antimicrobial activities. Further, the precise formulation of the composition products, i.e., in the anionic surfactant employed, is not disclosed. Therefore, no clear and convincing results are seen to be present over the cited prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 9, 12-16, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (GB 2 145 708) in view of Legros (WO91/04668 from the Information Disclosure Statement received June 21, 2000), Gerhold (WO96/14092), Bardoliwalla et al. (US Patent 4,599,372), West et al. (US Patent 4,602,011), and Davis et al. (EP 0491 391), references of record in the previous office action mailed July 31, 2001.

Davis '708 teaches an antimicrobial composition comprising THP and a dispersants, which are reasonably expected to enhance penetration of the active into organisms since enhanced dispersion of active agent throughout an area of water is expected to increase the number of water infecting organisms treated or contacted by the active at the same time. Davis teaches that both agents can be employed in the treatment of water to control the growth of microorganisms (See particularly page 1, line

5-14 and 63-65; and page 2, lines 21-25). Davis '708 also teaches the concentration of THP is 10-30 ppm (See particularly page 2, 3-10). Davis et al. also teaches the condensate of THP with urea may be used in the composition and method (See particularly claim 7).

Davis '708 does not expressly teach the use of a quaternary ammonium compound in the water treatment composition and method. Davis '708 does not expressly teach the use of poly[oxyethylene(dimethyliminio)ethylene(dimethyliminio)ethylene dichloride] in the water treatment composition and method. Davis '708 does not expressly teach the use of an alkyl benzene sulphonate having less than 5 aliphatic carbon atoms in the water treatment composition and method. Davis '708 does not expressly teach the use of glycol ether in the water treatment composition and method. Davis '708 does not expressly teach the use of phosphono polycarboxylic acid in the water treatment composition and method. Davis '708 does not expressly teach the use of 10 to 75% of THP and 0.1 to 10% of biopenetrant in the water treatment composition and method. Davis '708 does not expressly teach the use of surfactant in the water treatment composition and method.

Legros teaches the use of a quaternary ammonium compound in the water disinfecting composition and method (See particularly abstract; also page 3, line 1 – page 4, line 34; compound of formula I).

Gerhold teaches a biocidal composition and method employing poly[oxyethylene(dimethyliminio)ethylene(dimethyliminio)ethylene dichloride] as one of the active agent (See particularly page 5, line 14-16). In addition, Gerhold teaches that the biocidal

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composition and method may be used with surfactant (See particularly page 8, line 34- page 9, line 33). Moreover, Gerhold teaches that alkyl benzene sulphonate may be useful in forming the biocidal composition and method (See particularly page 9, line 13).

Bardoliwalla et al. teaches that methyl carbitol is useful in the waste water treatment composition (See particularly col.1, line 8-12 and also col.6, line 15-20; and claim 2).

West et al. teaches the employment of alkyl benzene sulphonate with a carbon side chain of two to 20 carbon atoms in an antimicrobial composition (See col.1, line 18-25; also col.4, line 15-18).

Davis '391 teaches that a phosphono polycarboxylic acid, 2-phosphono-1,2,4-tricarboxylbutane, may be used as a water treatment agent (See particularly page 2, line 16; and also page 4, line 28-36). Davis '391 also teaches the effective concentration of 2-phosphono-1,2,4-tricarboxylbutane should be 0.5 to 96% (See page 5, line 51-54).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate any of the agents herein into an antimicrobial water treatment composition and method with 10 to 75% of THP and 0.1 to 10% of biopenetrant.

One of ordinary skill in the art would have been motivated to incorporate any of the agents herein to form a antimicrobial water treatment composition and method with 10 to 75% of THP and 0.1 to 10% of biopenetrant because combining the agents herein which are known to be useful to antimicrobial, water treating methods individually into a

single composition and method useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Furthermore, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan, absent evidence to the contrary.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, examples 1-6 in the specification at page 17-22 have been considered but are not found persuasive as to the nonobviousness of the claimed composition and method invention for the treatment of aquatic systems to inhibit and prevent microbial growth. The data presented in example 1 has been considered but is not found persuasive as to unexpected results because data in example 1 merely compares the combination of the instant claimed composition against other commercial combination products. It is not clear whether those products are the closest standard for the comparison of antimicrobial activities. Further, the precise formulation of the composition products, i.e., in the anionic surfactant employed, is not disclosed. Therefore, no clear and convincing results are seen to be present over the cited prior art. The data of example 3 has been considered

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but is not found persuasive because data in example 1 merely compares the combination of the instant claimed composition against a control. The effectiveness of the THP composition in example 3 is seen to be an expected effect based on the cited prior art. No synergistic effect is seen to be present. Please note that the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data of examples 2, 4, and 6 merely demonstrate the effectiveness of the water treatment composition containing THP and an additional agent to inhibit or eradicate the bacteria in the water treatment method. This is seen to be an expected result based on the cited prior art. No comparison data to the closest prior art is presented in examples 2, 4, and 6. Therefore, no clear and convincing unexpected result is seen herein. The data of example 5 merely demonstrates the efficacy of different biopenetrants combined with THP in the water treatment method herein. The results have been considered and are seen to show an expected water-treatment effect based on the cited prior art. No clear and convincing unexpected results over the cited prior art is seen herein.

Response to Argument

Applicant's remarks filed January 16, 2002 regarding synergism being demonstrated in the specification have been considered and addressed under the rejection under 35 USC 112, first paragraph section.

Applicant's remarks filed January 16, 2002 regarding Davis'708 teaching only a combination of THP and the thiocyanate biocides, with no biopenetrant present have been considered but are not found persuasive because as discussed in the rejections under 35 USC 103 set forth above in the previous office action mailed July 31, 2001, THP is known to be used in a method of water treatment with a dispersant (See Davis'708 page 2, line 21-25). Dispersions are reasonably expected to enhance penetration of the active into organisms since enhanced dispersion of active agent throughout an area of water is expected to increase the number of water infecting organisms treated or contacted by the active at the same time. Therefore, the teaching of Davis'708 is seen to suggest the combination of THP with a biopenetrant agent.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the cited prior art clearly provides the motivation to combine the teachings of the cited prior art since

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combining all of the agents herein, which are known to be useful in antimicrobial water treatment individually, into a composition and method useful for the very same purpose is *prima facie* obvious. Please note that the motivation to combine the teachings of the cited prior art can come from either the teachings of the cited prior art or the general knowledge of persons of ordinary skill in the art (See MPEP 2143.01).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

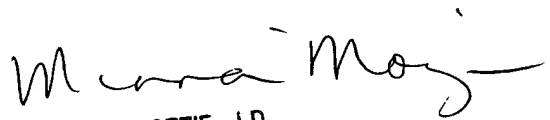
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
March 31, 2002


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600